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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/619,142	07/19/00	KNOWLES	W KNOWLES/HAIR

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HM42/0928

EXAMINER

KIM, V

ART UNIT	PAPER NUMBER
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1614

18

DATE MAILED:

09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/619,142

Applicant(s)

KNOWLES, W. RAY

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 6 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 16.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

DETAILED ACTION

Status of application

1. In accordance with the agreement made during a telephonic interview with Mr. Mark Pohl on August 09, 2001, the finality of the March 27, 2001. See the interview summary of paper no. 16. *is withdrawn.*
2. Claims 1-22 are pending in the application.
3. Acknowledgement is made of the declarations filed under Rule 131 and 132 on Feb. 12, 2001.
4. This instant office action supercedes any prior office action issued after 1st non-final office action of paper no. 5.

Claim Objections

1. Claims 8-10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recited use included in claims 8-10 fails to further limit any structural description of the constituents of the claimed composition.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "drop" in claims 5, 7, 16 and 18 is a relative term which renders the claims indefinite. The term "drop" is not defined by the claim and the specification does not provide a standard for ascertaining how much of something constitutes of "drop". Since "drop" is not a standard measuring method due to various influencing factors(e.g. viscosity, size of dropper, etc), the actual amount in the "drop" could be variable. Because the specification and the claims fail to teach the size of the dropper or comparable measurement for the drops claimed, one would not know what the metes and bounds of the claims are.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-4, 8-10, 12-15, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bazzano (US 5,183,817).

out

The claims 1-4 and 8-10 read on a composition comprising an effective amount of minoxidil and/or testosterone blocker such as progesterone, and a penetration enhancer. Claims 12-15 and 19-21 read on a method of preventing or treating alopecia using the said composition.

Bazzano (US'817) teaches all the critical elements. Specifically, Bazzano teaches a method of treating alopecia and a composition therefore wherein the composition comprises minoxidil(0.01-30%), retinoid and progesterone as active ingredients in a vehicles such as ethanol and propylene glycol, See the entire text and claims 1- 28, especially columns 3-4 & 19-20 and claim 28. Bazzano states " A major problem in influencing hair growth is obtaining good percutaneous absorption of the active compounds. The retinoid compounds causes excellent percutaneous absorption of themselves and other compounds used in combination therewith."-(see column 19, line 36-41). Thus, Bazzano also teaches that the retinoid as a penetration enhancer in addition to the utilization of propylene glycol or ethanol as a pharmacodynamically active carrier, which has also been notoriously known as a penetration enhancer in the art, See column 19, line 65-66. Thus, all the claimed critical elements are taught by the cited reference and all the claimed subject matter is anticipated.

out 3. Claims 1, 3, 11-12, 14, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bradbury(US 6,124,362)

Bradbury teaches a composition and a method for preventing and treating hair loss wherein said composition comprises a safe and effective amount of minoxidil(active ingredients) and isopropyl alcohol and propylene glycol as penetration enhancer; see

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example 5 and column 24, lines 32-40. It further states that the term "safe and effective amount" means an amount of an active ingredient high enough to modify the condition to be treated or to deliver the desired skin or hair benefit, but low enough to avoid serious side effects and the factors like penetration is critical, See column 25, lines 43-53 and column 5, lines 5-30. Sunscreen agent which is required by claims 11 and 22, is also taught in the patented disclosure as other active agent; see column 26, lines 48-65. All the elements are taught by the cited reference.

Thus the claimed subject matter is not patentably distinct over the prior art of the record.

3. Claims 1,3, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Partain III et al(US 4,946,870) or Rajadhyaksha (US 5,482,965).

The claims 1,3, 12 and 14 read on a composition comprising an effective amount of minoxidil and a penetration enhancer, and a method of preventing or treating alopecia using the said composition.

Partain III teaches anti-alopecia composition comprising minoxidil and chitosan derivatives(e.g.chitosonium niacinate);see example 7. Chitosan derivative as a effective penetration enhancer is taught in column 3, lines 53-60.

Rajadhyaksha teaches a hair growth promoting composition comprising minoxidil, penetration enhancers (e.g.5-amino-1,3-dioxane and ethanol); see example 18 and column 3, line 31 and abstract.

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-5, 7-11, 12-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoke (US5,994,319) alone, or if necessary, in view of Bradbury or Rajadhyaksha.

Hoke (US'319) teaches a synergistic composition for stimulating hair growth(restoring hair) and preventing alopecia (hair loss), comprising minoxidil(0.01-10%) and an inhibitor of steroid 5-alpha reductase in combination with delivery vehicles such as ethanol and propylene glycol. Hoke states that an inhibitor of steroid 5- α reductase inhibits the conversion of testosterone to dihydrotestosterone. Hoke also states that minoxidil used in conjunction with effectors of steroid metabolism, leads to enhanced hair growth and decreased rates of hair loss(alopecia), see abstract, column 3, lines 15-28 and column 6, lines 5-10. see abstract.

Applicant's claims differ because they require a penetration enhancer.

However, Hoke teaches a synergistic combination of minoxidil and an inhibitor of 5- α reductase. An inhibitor of 5- α reductase is also called as "a testosterone blocker" that is admitted by applicant in his own disclosure, See instant specification page 6. Hoke also suggests that various liposomal formulations may be added to the delivery vehicle to promote delivery to the hair follicle(i.e. penetration enhancer). Thus, it would have been obvious to one of ordinary skill in the art to modify the synergistic combination of minoxidil and an inhibitor of 5- α reductase(i.e. testosterone blocker) by adding a penetration enhancer to promote the delivery to the targeted site to maximize the therapeutic effect. One would ^{be} motivated to make this modification to lower the effective dosage of each active ingredient and to enhance the delivery wherein the modification results in lower side effects and optimal therapeutic efficacy.

In any event, Bradbury and Rajadhyaksha teaches the hair growth promoting effect of minoxidil is enhanced by adding penetration enhancers as mentioned in the 102 rejection above. Specifically, Rajadhyaksha teaches a hair growth promoting composition comprising minoxidil, penetration enhancers(e.g.5-amino-1,3-dioxane and ethanol); see example 18 and column 3, line 31 and abstract; and Bradbury specifically teaches a composition and a method for preventing and treating hair loss wherein said composition comprises a safe and effective amount of minoxidil(active ingredients) and isopropyl alcohol and propylene glycol as penetration enhancer. Thus, one would have been motivated to add penetration enhancers to the composition of Hoke to optimize its efficacy (i.e. improved therapeutic effects without undesirable side effects).

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3. Claims 2, 4-5, 7-10, 13, 15-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajadhyaksha in view of Bazzano.

Rajadhyaksha teaches a hair growth promoting composition comprising minoxidil and penetration enhancers (e.g. 5-amino-1,3-dioxane and ethanol); see example 18 and column 3, line 31 and abstract. Rajadhyaksha also teaches the utilization of progesterone in combination with a penetration enhancer; see example 29.

Applicant's claims differ because they require the combination of minoxidil and progesterone, and specific amount-ratios.

However, Bazzano teaches a composition comprising minoxidil and retinoid for treating and preventing alopecia as mentioned in the 102 rejection earlier. It also suggests that addition of optional active agent such as progesterone would; see US'817:claim 28, column 4, lines 8-12 and column 20, 5-20.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Rajadhyaksha to include testosterone blocker (i.e. progesterone) as taught by Bazzano to enhance the anti-alopecia effect of the minoxidil containing composition.

One would have been, thus, motivated to make this modification to improve the efficacy of Rajadhyaksha's composition even better because progesterone increases the rate of hair growth and/or retarding hair loss, effectively. The selection of optimal dosages and ratios in order to determine the most effective treatment is well within the skilled level of one having ordinary skill in the art, and is obvious.

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4. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajadhyaksha in view of Bazzano as applied to claims above, and further in view of Kita(US 6,162,801).

These claims 11 and 12 differ because they specifically require sunscreen. Even though Bazzano teaches vitamin D derivative such as cholecalciferol in the patented disclosure (see claim 27, column 4, lines 8-12 and column 20, 21-35), Bazzano is silent about the role of vitamin D derivative as a sunscreen. However it is noted that cholecalciferol is sunscreen as evidenced by Kita; see abstract.

In any event, Kita teaches that Vitamine D derivatives such as cholecaciferol protects the skin and scalp from harmful ultraviolet radiation and the utility of vitamin D containing dermatological composition; see abstract.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the said composition so as to include a further teaching as taught in Kita reference.

One would have been, thus, motivated to add vitamin D3 (i.e. cholecalciferol) and its derivative into an anti-alopecia formula comprising minoxidil in combination with progesterone, and a penetration enhancer, to improve not only anti-alopecia effect but also skin protection by adding a sunscreen.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields and share common utilities, and are pertinent to the problems that applicant is concern with. MPEP 2141.01(a).

Response to Amendment

1. The Declaration filed on Feb. 12, 2001 under 37 CFR 1.131 and 1.132 has been considered but is ineffective because of the reasons as follows:

a. The evidence submitted is insufficient to establish applicant's alleged actual reduction to practice of the invention in this country or a NAFTA or WTO member country after the effective date of the Hoke and Bradbury references.

b. The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Hoke and Bradbury references to either a constructive reduction to practice or an actual reduction to practice. Because all the dates in the submitted declaration have been blacked out, declaration fails to provide sufficient evidence to prove diligence.

c. The affidavit under rule 1.132 fails to provide evidence to prove patentability of applicant's instant claims 2, 4-11, 13 and 15-22 over the prior art of the record because the affidavit fails to demonstrate unexpected results wherein the comparison must cover the same limitations as the closest prior art relied upon and the claimed invention. It is noted that the exhibits only include minoxidil as an active ingredient, and not the testosterone blocker as set forth in these claims.

2. Therefore, the examiner's allegations regarding prima facie obviousness and anticipation based on the cited references in the previous office action would be sustained until these deficiencies are remedied.

3. This is non-final action because there are the new ground(s) of rejection added.

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4. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., penetration enhancers excluding propylene glycol and ethanol) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Allowable Subject Matter

1. Claim 6 and 17 are allowable but objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

2. The following is a statement of reasons for the indication of allowable subject matter: Kincl et al(1978) teach that an admixture of cholesterol trimethyl acetate and progesterone increases oral-bioavailability. However, it fails to teach a specific species (i.e.trimethyl acetate without any substituents) and topical application. Since skin layer is structurally different from oral mucosa or systemic absorption, it would not have been obvious over any prior of the record.

Conclusion

1. The claims 1-5 and 7-16 and 18-22 are rejected.

2. Claim 6 and 17 are allowable but objected.

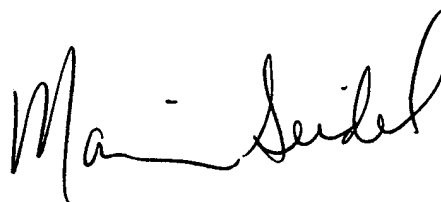
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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 746-3165.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
September 28, 2001

~~William Jarvis
Primary examiner
Art unit 1614~~



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